JAN 2 4 2002

K012534

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

1.	Submitter's Name:	Guidant Corporation Advanced Cardiovascular Systems, Inc.
2.	Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95054
3.	Telephone:	408-845-3956
4.	Fax:	408-845-3743
5.	Contact Person:	Joanna Mroz
6.	Date Prepared:	July 6, 2001
7.	Device Trade Name:	HI-TORQUE MIDDLE SUPPORT™ .012" Guide Wire with HYDROCOAT™ Hydrophilic Coating
8.	Device Common Name:	Guide Wire
9.	Device Classification Name:	Catheter Guide Wire (74DQX)
10.	Predicate Devices:	• ACS HI-TORQUE TRAVERSE® Guide Wire with HYDROCOAT™ Hydrophilic Coating • HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire with HYDROCOAT™ Hydrophilic Coating

11. Device Description:

The HI-TORQUE MIDDLE SUPPORT™ .012" Guide Wire with HYDROCOAT™ Hydrophilic Coating is a guide wire with a nominal diameter of 0.012". Like the ACS HI-TORQUE TRAVERSE® Guide Wire, the HI-TORQUE MIDDLE SUPPORT™ .012" Guide Wire is constructed from a stainless steel core. The distal segment of the guide wire includes a series of tapers and a flat, which reduce the diameter and stiffness of the distal core, thus yielding the desired flexibility and performance. The distal tip coil has a radiopaque length of 3 cm. The distal end of the guide wire is available either as a straight tip that is shapeable, or as a pre-shaped "J".

The HI-TORQUE MIDDLE SUPPORT™ .012" Guide Wire with HYDROCOAT™ Hydrophilic Coating is available in lengths of 190 cm and 300 cm exchange length. The 300 cm exchange length enables the physician ample working length of the guide wire to facilitate catheter exchanges. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE). The distal, coiled segment of the wire is coated with HYDROCOAT™ Hydrophilic Coating.

12. Intended Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible stent devices during therapeutic intravascular procedures.

13. Technological Characteristics:

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.

14. Performance Data:

In vitro bench testing and *in vivo* performance evaluations demonstrated that the HI-TORQUE MIDDLE SUPPORT™ .012" Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed similarly to the predicate devices. The following functional tests were performed: Distal Tip Pull (Tensile Strength), Distal Tip Turns-to Failure (Torque Strength), Rotational Accuracy (Torqueability), and Tip Flexibility. In addition, two performance evaluations in an *in vivo* animal model were conducted. The devices performed comparably to the predicate devices and no new safety or effectiveness issues were raised during the testing program Therefore, the HI-TORQUE MIDDLE SUPPORT™ .012" Guide Wire with HYDROCOAT™ Hydrophilic Coating may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2002

Ms. Joanna Mroz
Regulatory Affairs Coordinator
Guidant Corporation
3200 Lakeside Drive
Santa Clara, CA 95054-2807

Re: K012534
HI-TORQUE MIDDLE SUPPORT™ 0.012" Guide Wire with HYDROCOAT™ Hydrophilic Coating
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 29, 2001
Received: December 4, 2001

Dear Ms. Mroz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012534

Device Names:
- HI-TORQUE MIDDLE SUPPORT™ .012" Guide Wire with HYDROCOAT™ Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal angioplasty (PTA) and compatible stent devices during therapeutic intravascular procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012534